

4176-101

**Section II. REMARKS****(I). Approval of Proposed Drawing Correction, and Acceptance of Formal Drawing**

Applicant acknowledges the approval of the proposed drawing correction submitted on June 23, 200 and acceptance of the concurrently submitted correspondingly corrected formal drawing (paragraphs 10 and 11 of the PTOL-326 form in the July 1, 2004 Office Action).

**(II). Missing PTO-1449 Page of IDS Submitted July 2, 2001**

A copy of the applicant's PTO-1449 form, stated in the Attachments section of the PTOL-326 form to be a "missing page" of such IDS, has been attached to the July 1, 2004 Office Action (page 3 of 3 of the July 2, 2001 IDS). Such sheet has now been initialed in the entries for references BE-BK by Examiner Walicka to complete the record for such IDS.

**(III). Rejection of Claims on Section 112, Second Paragraph Grounds**

In the July 1, 2004 Office Action, claim 78 has been rejected as lacking proper antecedent basis for "the phrase transition temperature" [sic- the Office Action contained a misspelling of the word "phrase" which should have been "phase"].

In response, claim 78 has been amended to recite the fusion protein as having "a phase transition temperature in a range of from about 35 to about 60°C," thereby overcoming such rejection.

In response to the rejection of claim 31 as being a substantial duplicate of allowed claim 12, the subject matter of claim 12 has now been incorporated in claim 1 (see discussion below) and claim 31 has been amended to incorporate therein the following limitations:

**"wherein the one or more biological molecules of (a) is proteolytically cleavable from the fusion protein; and**

**wherein the phase transition is mediated by one or more means selected from the group comprising: changing temperature; changing pH; addition of solutes and/or solvents, side-chain ionization or chemical modification; and changing pressure."**

4176-101

Accordingly, the rejection of claim 31 has been overcome by such amendment.

In response to the rejection of claim 74 as being a duplicate of claim 72, claim 74 has been amended to place same into dependent form under amended claim 1. Concurrently, since claim 75 as previously presented depended from claim 74, claim 75 has been further amended to depend from claim 72.

Claim 74 as amended therefore overcomes the rejection.

In addition to the foregoing, claim 70 has been amended herein, to depend from claim 69, thereby providing appropriate antecedent basis for "the salt."

**(IV). Amendment of Claims 1, 13-19 and 81 to Overcome §112, First Paragraph Rejection**

In response to the rejection of claims 1, 2-10, 21-26, 66-70, 79, 80 and 81 under 35 U.S.C. §112, first paragraph, claims 1 and 81 have been amended herein consistent with the examiner's discussion of the reason for allowance of claims 12-19, 27-28, 32, 71-72, 75 and 82 (page 4, July 1, 2004 Office Action).

Thus, the substance of allowable claim 12 has been incorporated in claim 1. Correspondingly, claim 12 has been cancelled, and claims 13-19 and 76 have been amended to place same into dependent form under amended claim 1.

Claim 81 has been amended to recite therein the following limitations:

**"wherein the one or more phase transition proteins of (b) comprises at least thirty repeats of the pentapeptide Val-Pro-Gly-X-Gly, in which X is any natural or non-natural amino acid residue,**

**wherein the phase transition is mediated by one or more means selected from the group comprising: changing temperature; changing pH; addition of solutes and/or solvents, side-chain ionization or chemical modification; and changing pressure,"**

to thereby place such claim in condition for allowance, consistent with the examiner's allowance of claim 27 containing the same following limitation:

4176-101

“wherein the one or more phase transition proteins of (b) comprises at least thirty repeats of the pentapeptide Val-Pro-Gly-X-Gly, in which X is any natural or non-natural amino acid residue.”

**(V). Summary of Patentable Character of Claims 1, 3-10, 13-19, 21-28, 31, 32, 66-72, 74-76 and 78-82 Pending in Application**

With the above-discussed amendment of claims 1, 31, 74, 75, 78 and 81 herein, all pending claims 1, 3-10, 13-19, 21-28, 31, 32, 66-72, 74-76 and 78-82 are now in form and condition for allowance.

Set out below is a statement of patentability for each of such pending claims.

<b>Claim</b>	<b>Reasons for Patentability</b>
1	Limitation of allowed claim 12 has been incorporated in claim 1
3	Dependent from claim 1
4	Dependent from claim 1
5	Dependent from claim 1
6	Dependent from claim 1
7	Dependent from claim 1
8	Dependent from claim 7, which in turn is dependent from claim 1
9	Dependent from claim 1
10	Dependent from claim 1

4176-101

12	Allowed in July 1, 2004 Office Action; cancelled and subject matter thereof incorporated in claim 1 to place claim 1 in allowable form
13	Amended to depend from claim 1; allowed in July 1, 2004 Office Action
14	Amended to depend from claim 1; allowed in July 1, 2004 Office Action
15	Amended to depend from claim 1; allowed in July 1, 2004 Office Action
16	Amended to depend from claim 1; allowed in July 1, 2004 Office Action
17	Amended to depend from claim 1; allowed in July 1, 2004 Office Action
18	Amended to depend from claim 1; allowed in July 1, 2004 Office Action
19	Amended to depend from claim 1; allowed in July 1, 2004 Office Action
21	Dependent from claim 1
22	Dependent from claim 1
23	Dependent from claim 22, which in turn is dependent from claim 1
24	Dependent from claim 22, which in turn is dependent from claim 1
25	Dependent from claim 1
26	Dependent from claim 1
27	Allowed in July 1, 2004 Office Action
28	Allowed in July 1, 2004 Office Action

4176-101

31	Rejected only for being a duplicate of claim 12; now amended to incorporate additional limitations noted in Section III above, to demarcate from amended claim 1
32	Dependent from claim 31
66	Dependent from claim 9, which in turn is dependent from claim 1
67	Dependent from claim 66
68	Dependent from claim 66
69	Dependent from claim 68
70	Dependent from claim 69
71	Allowed in July 1, 2004 Office Action
72	Allowed in July 1, 2004 Office Action
74	Dependent from claim 1
75	Dependent from claim 72
76	Dependent from claim 1
78	Rejected only on lack of antecedent basis for terminology; now amended to overcome such §112, 2 <sup>nd</sup> Paragraph rejection
79	Dependent from claim 1
80	Dependent from claim 21, which in turn is dependent from claim 1
81	Amended as discussed in Section IV hereof, to place the claim in condition for allowance, consistent with the examiner's allowance of claim 27 containing the same limitation of repeats of VPGXG pentapeptide sequence

4176-101

82	Allowed in July 1, 2004 Office Action
----	---------------------------------------

**CONCLUSION**

Based on the amendments made herein and the foregoing remarks, pending claims 1, 3-10, 13-19, 21-28, 31, 32, 66-72, 74-76 and 78-82 are now in form and condition for allowance.

Respectfully submitted,



---

Steven J. Hultquist  
Reg. No. 28,021  
Attorney for Applicant

**INTELLECTUAL PROPERTY/  
TECHNOLOGY LAW**  
P.O. Box 14329  
Research Triangle Park, NC 27709  
Telephone: (919) 419-9350  
Fax: (919) 419-9354  
Attorney Ref: 4176-101